REMARKS

This Response is made to the Official Action mailed May 20, 2009. Claims 1-25 are currently pending in this application. The subject matter of the claims is subject to a requirement for restriction and election under 35 U.S.C. §§121 and 372. Reconsideration and withdrawal of the requirements for restriction and election of species are respectfully requested in view of the following remarks.

Applicants are required to make an election among four inventions which the Examiner states are allegedly not linked to form a single general inventive concept under PCT Rule 13.1, namely:

I. Claim 14, drawn to piperidinyl indoles i.e., formula I when Z^1 is piperdine classified in class 546, subclass 201+ depending on species election. Generic claims 1-11, 13, 15-22 reading on the elected compounds can be prosecuted with the elected compounds to the extent of the election. If this group is elected, a further election of a single disclosed species is also required.

II. Claim 12, drawn to non-heterocyclic substituted indoles i.e., formula I when Z^1 is phenyl optionally substituted, classified in class 548, subclass various, depending on species election. Generic claims 1-11, 15-22 reading on the elected compounds can be prosecuted with the elected compounds to the extent of the election. If this group is elected, a further election of a single disclosed species is also required.

III. Claims 1-11, 13, 15-22, drawn to remaining compounds of formula I, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species is also required and further restriction depending on the species election would be made.

IV. Claims 23-25, drawn to method of treating disorder associated with IKK2 activity classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a single disclosed disorder and a single disclosed compound effective on treating the elected disorder is also required.

Applicants respectfully traverse the requirement for restriction initially because it does not comply with the unity of invention standard set by the PCT, and secondly, because it is improper under U.S. restriction practice since there would be no additional burden upon the Examiner to search all Groups together.

The standard applicable to the instant application is not one of restriction practice under U.S. guidelines, but one of unity of invention under the PCT. In the instant case, no lack of unity of invention was found by the International Searching Authority or the International Preliminary Examining Authority, and all claims were searched and examined as one invention. The question of unity of invention may be reexamined only within the scope of rules of the Patent Cooperation Treaty (35 U.S.C. §372(b)), and restriction requirements made according to U.S. practice, which are more restrictive than the PCT regulations, are in error. PCT Article 27 ("no national law shall require compliance with requirements relating to form or contents ... different from or additional to those which are provided for in this Treaty and the Regulations").

PCT Rule 13.1 states that there exists unity of invention if the international application relates "to one invention only or to a group of inventions so linked as to form a single general inventive concept." Clearly the general inventive concept which links the alleged various inventions here is a structural class of compounds having a common pharmacological activity. PCT Rule 13.2 states that unity of invention shall be fulfilled where there is a technical relationship among those inventions involving one or more of the same or corresponding technical features, where the technical feature defines the contribution that each of the claimed inventions makes over the prior art. The special technical features shared by each of the various Groups which the Examiner has deemed distinct are (i) the indole carboxamide nucleus of the instant compounds, and (ii) the common IKK2 inhibition activity of the compounds. Since the various compounds are related to the same underlying technical features, there is unity of invention and a restriction requirement is improper.

Furthermore, in accordance with U.S. practice, M.P.E.P. §803 mandates two criteria for a proper restriction requirement: 1) the inventions must be independent or distinct as claimed; and 2) there must be a serious burden on the Examiner if restriction is not required.

It is urged that the above Groups are merely different embodiments of a single inventive concept for which a single patent should issue and do not constitute distinct

inventions such as to require that the subject matter be prosecuted in separate patent applications. "Independent", according to M.P.E.P. §802.01, means that "there is no disclosed relationship between the two or more subjects disclosed." The subject matter of Groups I - IV are clearly related, having arisen from a singular research effort, as related to novel compounds having a common structural core nucleus and having their genesis in a common pharmacological activity. Therefore, the Groups are not independent inventions within the meaning of §802.01. Furthermore, since the compounds have a core nucleus of structure there is not an undue burden on the Examiner with respect to searching the subject matter of the invention.

Therefore, in view of the foregoing and further in view of the interest of efficiency and cost savings to both Applicants and the PTO, reconsideration and withdrawal of the requirements for restriction and election are requested. However, Applicants provisionally elect, subject to the traverse set forth above, Group I, covering claim 14 drawn to piperidinyl indoles i.e., formula (I) when Z^1 is piperdine classified in class 546, subclass 201+ depending on species election. Claims 1-11, 13, 15-22 are generic to the elected subject matter. The species elected is a compound of formula (I) which is 3-(1-ethyl-3-piperidinyl)-5-phenyl-1H-indole-7-carboxamide (see Example 45). In the event the requirement is made final, Applicants hereby reserve the right to file one or more divisional applications directed to the non-elected subject matter.

In view of the above remarks, reconsideration and allowance of this application with claims 1-25 are earnestly solicited.

Respectfully Submitted,

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